CLAIMS

The invention claimed is:

1. A method of treating chronic lymphocytic leukemia in a human subject, said method comprising administering to said subject at least one cycle of concurrent therapy with an anti-CD52 antibody and an interleukin-2 (IL-2).

2. The method of claim 1, wherein said IL-2 is recombinantly produced IL-2 having an amino acid sequence for human IL-2 or a variant thereof having at least 70% sequence identity to the amino acid sequence for human IL-2.

3. The method of claim 2, wherein said variant thereof is des-alanyl-1, serine 125 human interleukin-2.

4. The method of any one of claims 1, 2 and 3, wherein said anti-CD52 antibody is an immunologically active anti-CD52 antibody.

5. The method of claim 4, wherein said anti-CD52 antibody is Alemtuzumab or fragment thereof.

6. A method of treating chronic lymphocytic leukemia in a human subject, said method comprising administering to said subject at least one cycle of concurrent therapy with an anti-CD52 antibody and an interleukin-2 (IL-2), wherein said cycle comprises administering a therapeutically effective dose of an anti-CD52 antibody according to a weekly, twice-weekly, or thrice-weekly dosing schedule in combination with administration of a constant IL-2 dosing regimen, said constant IL-2 dosing regimen comprising administering a total weekly dose of an IL-2 to said subject.

7. The method of claim 6, wherein a first dose of an IL-2 is administered to said subject concurrently with a first dose of an anti-CD52 antibody.

8. The method of claim 7, wherein a first dose of an IL-2 is administered to said subject one week after a first dose of an anti-CD52 antibody is administered to said subject.

9. The method of any one of claims 6 and 7, wherein said IL-2 is recombinantly produced IL-2 having an amino acid sequence for human IL-2 or a variant thereof having at least 70% sequence identity to the amino acid sequence for human IL-2.

10. The method of claim 9, wherein said variant thereof is des-alanyl-1, serine 125 human interleukin-2.

11. The method of claim 6, wherein said anti-CD52 antibody is an immunologically active anti-CD52 antibody.

12. The method of claim 11, wherein said anti-CD52 antibody is Alemtuzumab or fragment thereof.

13. The method of claim 6, wherein one or more subsequent cycles of concurrent therapy with IL-2 and anti-CD52 antibody is initiated about 1 month to about 6 months following completion of a first cycle or completion of any subsequent cycles of concurrent therapy with IL-2 and anti-CD52 antibody.

14. The method of claim 13, wherein T-cell counts are monitored in said subject to determine when each of said cycles is initiated, said cycles being initiated when T-cell count is less than 80% of the T-cell count at the conclusion of any previous cycle of concurrent therapy with an IL-2 and an anti-CD52 antibody.

15. The method of claim 6, wherein said total weekly dose of an IL-2 is in an amount that provides at least 50% of the NK stimulatory activity of a total weekly dose of Aldesleukin administered in a range of from about 1100 μg to about 1834 μg.

16. A product containing an anti-CD52 antibody and an IL-2 as a combined preparation for simultaneous, separate, or sequential use in CLL therapy.

17. The product of claim 16, wherein said anti-CD52 antibody is an immunologically active anti-CD52 antibody.

18. The product of claim 16, wherein said anti-CD52 antibody is Alemtuzumab or fragment thereof.

19. The product of claim 16, wherein said anti-CD52 antibody is a human anti-CD52 antibody, a humanized anti-CD52 antibody, or a chimeric anti-CD52 antibody.

20. The product of any one of claims 16, 17, 18, and 19, wherein said IL-2 is recombinantly produced IL-2 having an amino acid sequence for human IL-2 or a variant thereof having at least 70% sequence identity to the amino acid sequence for human IL-2.

21. The product of claim 20, wherein said variant thereof is des-alanyl-1, serine 125 human interleukin-2.

22. Use of an interleukin-2 (IL-2) in the preparation of a medicament for treating chronic lymphocytic leukemia (CLL) in a human subject previously administered with, or receiving administration of, an anti-CD52 antibody.

23. Use of an anti-CD52 antibody in the preparation of a medicament for treating CLL in a human subject previously administered with, or receiving administration of, an IL-2.

24. Use of an IL-2 in the preparation of a medicament for treating CLL in a human subject by separate, sequential or simultaneous administration with an anti-CD52 antibody.

25. Use of an anti-CD52 antibody in the preparation of a medicament for treating CLL in a human subject by separate, sequential or simultaneous administration with an IL-2.

26. Use of an anti-CD52 antibody and an IL-2 in the preparation of a medicament for treating

CLL in a human subject by separate, sequential or simultaneous administration of the anti-CD52 antibody and the IL-2.

27. Use of an IL-2 in the preparation of a medicament for increasing or maintaining T-cell count in a human subject previously administered with, or receiving administration of, an anti-CD52 antibody.

28. Use according to any of claims 22 to 27 wherein the anti-CD52 antibody is administered to the subject according to a weekly, twice-weekly or thrice-weekly dosing schedule.

29. Use according to any of claims 22 to 28 wherein the IL-2 is administered to the subject according to a constant dosing regimen comprising administering a total weekly dose of an IL-2 to the subject.

30. Use according to claim 29 wherein a first dose of the IL-2 is administered to the subject simultaneously with a first dose of the anti-CD52 antibody.

31. Use according to claim 29 wherein a first dose of the IL-2 is administered to the subject one week after a first dose of the anti-CD52 antibody.

32. Use according to any of claims 29 to 31, wherein the total weekly dose of the IL-2 is in an amount that provides at least 50% of the NK stimulatory activity of a total weekly dose of Aldesleukin administered in a range of from about 1100 μg to about 1834 μg.

33. A kit comprising an anti-CD52 antibody, an IL-2 and instructions for administering the IL-2, separately, simultaneously or sequentially with administration of the anti-CD52 antibody, to an individual suffering from CLL.

34. A kit according to claim 33 wherein the instructions are to administer the IL-2 following the administration of the anti-CD52 antibody.

35. A use or a kit according to any of claims 22 to 34, wherein said IL-2 is recombinantly produced IL-2 having an amino acid sequence for human IL-2 or a variant thereof having at least 70% sequence identity to the amino acid sequence for human IL-2.

36. A use or a kit according to claim 35, wherein said variant thereof is des-alanyl-1, serine 125 human interleukin-2.

37. A use or a kit according to any of claims 22 to 36, wherein said anti-CD52 antibody is an immunologically active anti-CD52 antibody.

38. A use or a kit according to claim 37, wherein said anti-CD52 antibody is Alemtuzumab or a fragment thereof.

39. A use or a kit according to claim 37, wherein said anti-CD52 antibody is a human anti-CD52 antibody, a humanized anti-CD52 antibody, or a chimeric anti-CD52 antibody.